IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC., Plaintiff, v. IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC, and ALCON INC., Defendants.	)	**Redacted - Public Version** C.A. No. 21-1317-GBW-SRF [redacted]

DEFENDANTS' OPENING BRIEF IN SUPPORT OF ITS MOTIONS FOR SUMMARY JUDGMENT OF INVALIDITY

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Dated: October 12, 2023

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In exchange for patent protection, a patentee must disclose an invention to the public and describe it in a way that a person of ordinary skill can make and use the entirety of the claimed invention. *Amgen Inc. v. Sanofi*, 598 U.S. 594, 604-05 (2023). That is the fundamental "*quid-pro-quo* premise of patent law." *Id.* at 604. If, however, the "inventor claims a lot, but enables only a little, the public does not receive its benefit of the bargain." *Id.* at 616. In that situation, the patent is invalid. That is true here, where the inventors claimed to have invented a lot, but disclosed very little, because they knew very little and were not in possession of the claimed invention.

In 2006, Paul Badawi, a venture capital investor, and David Badawi, an ophthalmologist who did not specialize in glaucoma, filed a patent application (the parent application to the Asserted Patents) covering a "support" that "does not significantly block" flow of aqueous humor (a fluid produced in the eye) when implanted within a part of the eye called "Schlemm's canal." That "does not significantly block" limitation ("Block Limitation") is the focus of this motion. Neither "inventor" had any experience in biomedical engineering, fluid dynamics, or stent design. [redacted], and their application's specification (common to all Asserted Patents) gave no functional examples. In fact, four years later, they still had no embodying prototype. [redacted] To this day, seventeen years after submitting the parent application, the "inventors" still have no commercial embodiment of their "support" because they did not then and do not now possess the invention. As a result, neither does the public, which violates the *quid-pro-quo* premise of patent law.

Fifty-five of the eighty-six asserted claims in this case claim each and every "support" that "does not significantly block" flow when implanted within Schlemm's canal, but the specification

lacks the basic information that would have allowed a skilled artisan to (1) make and use the full scope of the invention without undue experimentation, which renders the claims invalid for lack of enablement; (2) recognize the inventors actually possessed all supports that achieve the "does not significantly block" function encompassed by the claims, which renders the claims invalid for lack of written description; or (3) be reasonably certain whether or not a given "support" "does not significantly block" flow when implanted, which renders the claims invalid for indefiniteness. Summary judgment is the appropriate time to invalidate these functional claims and narrow the issues for trial. There is no genuine dispute that the common specification is no more than a trial-and-error research plan for an unpredictable problem requiring immense resources and time for a person of ordinary skill to solve: it contains no functional examples, no representative "supports," and no common structural features to distinguish a support that "does not significantly block" flow from one that does. Discovering a solution to this kind of functional problem requires "undue experimentation," robbing the public of the make-and-use benefit it is supposed to receive in exchange for granting a limited monopoly. The claims should be held invalid as a matter of law.

In addition, Sight seeks to impermissibly extend its patent monopoly by not limiting the terms of the '361 and '443 patents to the expiration dates of the related '328 and '742 patents, whose claims Sight admits are not patentably distinct from the '361 and '443 patents. This is obviousness-type double patenting ("ODP"), which is a separate, independent basis for summary judgment of invalidity of the '361 and '443 patents.

I. NATURE AND STAGE OF PROCEEDINGS

Sight Sciences, Inc. filed this suit on September 16, 2021. Fact discovery closed June 29, 2023, and expert discovery closed September 28, 2023. Trial is scheduled to begin April 8, 2024.

II. SUMMARY OF THE ARGUMENT

1. ***Motion 1: Enablement.*** The Block Limitation claims are invalid for lack of

enablement as a matter of law because they attempt to monopolize every support that "does not significantly block" fluid flow, without any guidance in the specification as to which among a potentially infinite number of configurations would achieve that function. To determine which combinations of size, shape, orientation, radii of curvature, and materials would achieve that function, Sight's expert admits that a person of ordinary skill in the art (POSA)[1] would have to conduct expensive and extensive trial-and-error testing without any guarantee of success. That is undue experimentation as a matter of law because it leaves it to a POSA to "engage in painstaking experimentation to see what works. That is not enablement." *Amgen*, 598 U.S. at 614.

2. ***Motion 2: Written Description.*** The Block Limitation claims do not satisfy the written description requirement because the Asserted Patents' disclosure is insufficient as a matter of law to demonstrate that the inventors "possessed" or "actually invented" the functionally defined genus of claimed "supports." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). The universe of potential supports covered by the claims is immeasurable, with no disclosed common structural feature to achieve the claimed Block Limitation function. [redacted], and the specification contains ***zero*** examples demonstrating a support that actually achieves the claimed function. Instead, the Asserted Patents do no more than set forth a "mere wish or plan for obtaining the claimed invention," which "is not adequate written description." *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011) (reversing a denial of JMOL and holding claims invalid for inadequate written description).

3. ***Motion 3: Indefiniteness.*** These same functional limitations render the claims

[1] The parties' proposed definitions of a POSA do not materially differ for purposes of summary judgment. *See* D.I. 118 at 4-5 (both definitions including an ophthalmologist and/or engineering degrees with experience in implants); Ex 16, Downs Reb. Rep. ¶ 24, 1073.

indefinite. The Court's construction replaces one relative term of degree ("substantially") with another ("significantly"), and a POSA would not have been reasonably certain of the scope of the claims. Indeed, the claimed "support" may achieve the result in some patients but not others. And although the Court adopted Sight's reasoning when it construed the "does not significantly block" term, tying it to an "increase in aqueous outflux (and therefore a decrease in [intraocular pressure]) [in the eye,]" D.I. 273 at 6, Sight's expert now requires that one show that fluid in the eye (aqueous humor) flows through specific tissue (the trabecular meshwork) to meet the claim. But the specification has no guidance for how to determine ***where*** the fluid flows. This added requirement that cannot be measured injects more uncertainty and confirms the claims are indefinite.

4. ***Motion 4: Obviousness-type double patenting.*** The '361 and '443 Asserted Claims are invalid for yet another reason: ODP. Sight does not dispute that these patents expire after the '328 and '742 patents, or that Sight has not filed a terminal disclaimer for these patents. ODP CSoF at ¶¶1–4, 6. And Sight has previously admitted these claims are not patentably distinct. ODP CSoF at ¶¶5,7–10. A side-by-side comparison of the claims confirms this. Appendix X. The '361 and '443 patents are therefore invalid for ODP. *In re: Cellect, LLC*, 81 F.4th 1216, 1226 (Fed. Cir. 2023).

III. ARGUMENT

A. Motion 1: The Block Limitation Claims Are Invalid for Lack of Enablement Because the Universe of Supports That Could Potentially Achieve the Claimed Function Is Infinite and Undue Experimentation Would be Required to Determine the Full Scope

Fifty-five of the eighty-six Asserted Claims cover any "support" defined not by the support's structure but its ***functionality*** (*i.e.*, by the result it achieves when implanted in the eye). The claims ***functionally*** restrict the invention to a support that "does not significantly block" fluid flow. D.I. 287. Courts routinely find that such broad functional limitations "pose high hurdles in

fulfilling the enablement requirement" and are invalid unless the specification explains ***what it is about the invention that provides the claimed function***. *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1087 (Fed. Cir. 2021); *see also id.* at 1085-86 (collecting cases). "The more one claims, the more one must enable." *Amgen*, 598 U.S. at 610. In such a case, a patent must give even more guidance through "exact terms" that would "enable a person skilled in the art" to make and use the ***full scope*** of the claimed invention without undue experimentation. *Id.* "[I]f an inventor claims a lot, but enables only a little, the public does not receive its benefit of the bargain." *Id.* at 616. It is the fundamental "*quid-pro-quo* premise of patent law" that the inventor benefit society with instructions for how to make and use the invention in exchange for patent protection. *Id.* at 604-05; *see also Amgen*, 987 F.3d at 1084.

Sight's Asserted Claims with the Block Limitation fall well short of the enablement standard because they "claim[] a lot," but the specification "enables only a little." The Court adopted Sight's proposed construction of the Block Limitation to mean "the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels." D.I. 287. Yet, the specification does not explain what feature of a "support" or method of implanting a "support" ensures it meets the Block Limitation. During claim construction, Sight asserted, and this Court agreed, that "a skilled artisan would evaluate whether a support 'substantially interferes' or 'significantly blocks' fluid flow in the eye 'by determining whether an increase in aqueous outflux (and therefore a decrease in [intraocular pressure]) has been achieved by the support.'" D.I. 273 at 6; *see also id.* at 7 (similar); D.I. 119 Ex. 20 at 141:18-142:8 (Sight's expert testifying only "net increase in fluid efflux" is important). Making that determination, and understanding the full scope of "supports" that achieve that function, requires a POSA to undertake extensive experimentation—testing all potential supports in time-consuming

studies and analyzing whether they increase aqueous outflux. Ex. 24, 9/28 Downs Tr. 86:6-19, 87:13-88:22, 98:10-100:11, 103:5-15; 105:23-106:5. That is "'painstaking experimentation' to see what works[,]…not enablement. More nearly, it is 'a hunting license.'" *Amgen*, 598 U.S. at 614.

Confirming the enablement problem, Sight's expert now says the Court's construction requiring increased aqueous outflow or intraocular pressure (IOP) reduction is insufficient, opining that the Block Limitation further ***requires*** that fluid flow across the trabecular meshwork. Ex. 24, 9/28 Downs Tr. 107:5-108:12 ("I believe that the blocking term…requires some flow to be shown across the trabecular meshwork operating as a filtering tissue"); 147:22-149:3. Yet, as Sight's expert admits, it is not physically possible to determine the flow pathway for all possible devices. *Id.* 14:13-18; 64:10-65:24; 112:22-114:17; 157:14-158:13; Ex. 23, 9/22 Downs Tr. 231:8-232:25; *see also Trs. of Boston Univ. v. Everlight Elecs. Co.*, 896 F.3d 1357, 1361 (Fed. Cir. 2018) ("We can safely conclude that the specification does not enable what the experts agree is physically impossible."). Under either the Court's IOP reduction or Sight's pathway view, the Block Limitation renders the claims invalid for lack of enablement.

Enablement is a question of law, and an analysis of the so-called *Wands* factors (listed in the headings below) courts use to determine whether a claim would require "undue experimentation" to practice the claim's full scope as of the priority date show the Block Limitation claims are not enabled. *See Amgen*, 987 F.3d at 1084, 1086-87 (citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) and collecting cases); *see also Baxalta Inc. v. Genentech, Inc.*, No. 2022-1461, 2023 WL 6135930, at *4 (Fed. Cir. Sept. 20, 2023) (affirming summary judgment of lack of enablement).

The Breadth of the Claims. The potential breadth of the Block Limitation claims is vast. There is no "quality common" to all "supports" that dictates whether or not the support achieves

the Block Limitation function when implanted within Schlemm's canal, and no discussion that any of the disclosed "supports" are functional. *Amgen*, 598 U.S. at 600, 610-11. The "support" is the only "quality common" to all the Block Limitation claims, but Sight admits that "support," *i.e.*, a prop, is "used in a broad way" and "not limited." Ex. 60, 2/9/23 *Markman* Hr'g Tr. 12:2-8; 37:21-25; Ex. 24, 9/28 Downs Tr. 36:11-16; D.I 287 (construing "support" as "a prop" or "a structure that props something open"). The "support" is bounded only by whether it fits inside Schlemm's canal; otherwise, it can be virtually any shape, configuration, size/thickness, length, type of structure, or biocompatible material.[2] As Sight's expert agreed, "[t]here are lots of potential designs that could meet the claim limitations," and the claims cover various "combinations of materials," "radii of curvature," sizes, and configurations. Ex. 24, 9/28 Downs Tr. 35:7-25. And even though the Asserted Patents disparage and teach away from bypass stents (Ex. 1, '482 Patent at 2:22-28), Sight contends these are, too, are within the apparently boundless scope of the Asserted Claims (because the accused Hydrus is a trabecular bypass stent). D.I. 59 ¶¶ 55, 102-131; *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1379 (Fed. Cir. 2007) ("[W]here the specification teaches against a purported aspect of an invention, such a teaching is itself evidence that at least a significant amount of experimentation would have been necessary to practice the claimed invention.") (quotation omitted).

The structural features in ***some*** claims—radius of curvature, fenestrations, surface area contact—do not appear in ***all*** claims and thus cannot be a "quality common" to all "supports" that

[2] *See* Ex. 1, '482 Patent at Figs. 5A-12H; 5:39-48; 10:40-60; 11:42-12:22 (disclosing any possible configuration, including "zig-zag," "open network," "sinusoidal," and "arcuate"); *id.* at Figs. 10A-C, 4:4-10, 11:39-45 (disclosing lengths up to the entire circumference of the canal); *id.* at 9:25-36, 3:53-58, 9:45-48 (taking "any suitable shape" and can be hollow, closed, open, solid, porous, "or any combination thereof"); *id.* at 2:66-3:33; 3:54-56; 12:55-13:46 (listing hundreds of possible materials from which the support can be made); Ex. 24, 9/28 Downs Tr. 60:19-61:1.

enables the functionality of the Block Limitation. *Amgen*, 598 U.S. at 600, 610-11. As Sight's expert acknowledges, such features appearing in some of the claims do not alone achieve the function. Ex. 24, 9/28 Downs Tr. 145:25-146:13. Thus, the Block Limitation claims have only "support" as a common feature and are hopelessly broad.

Nature or field of the invention; the state of the prior art; the level of skill of a POSA; and the predictability or unpredictability of the art. Enablement is assessed as of the priority date of the patent. *In re '318 Pat. Infringement Litig.*, 583 F.3d 1317, 1323 (Fed. Cir. 2009). There is no genuine dispute that, as of the Asserted Patents' 2006 priority date, it would have been highly unpredictable to a POSA in the glaucoma implant field whether or not a Schlemm's canal implant would achieve the Block Limitation function when implanted in an eye. *See In re Fisher*, 427 F.2d 833, 839 (CCPA 1970) (describing "physiological activity" as an "unpredictable factor" and holding claims not enabled). Indeed, the inventors' inability to show that even their own stent, developed four years after 2006, could achieve the Block Limitation function without iterative testing demonstrates the unpredictability in this field.

[redacted]. *See* Ex. 25, D. Badawi Tr. 164:12-17; Ex. 26, P. Badawi Tr. 146:7-11. [redacted]. Exs. 54-55, SGHT0161700-703; Ex. 25, D. Badawi Tr. 171:3-172:22,174:24-175:15; Ex. 52, SGHT0030772 ([redacted]). [redacted]

[3] Perfusion tests are *ex vivo* studies using cadaver eyes to experimentally measure changes to fluid outflow and intraocular pressure, for example, after implanting a Schlemm's canal stent. D.I. 119, Ex. 20 at 123:2-6; *id*. Ex. 17 at 989-991.

[redacted] (Exs. 54-55, SGHT0161701-703; Ex. 25, D. Badawi Tr. 184:2-185:5), [redacted][4] In fact, [redacted]. Ex. 25, D. Badawi Tr. 175:16-177:5; 178:3-25; 181:12-16; 184:2-185:5. [redacted] *Id.* 122:23-123:5; *see also id.* at 96:22-25. Sight's expert also agrees that testing or modeling is ***required*** to determine whether a support has the claimed functionality, further demonstrating the unpredictability in the field. Ex. 24, 9/28 Downs Tr. 87:13-88:22; 98:10-100:11; 105:23-106:5.

Sight's expert has concocted a new, membrane-specific construction of the Block Limitation that further demonstrates the field's unpredictability and confirms these functional claims are not enabled. Sight's expert opines that the Block Limitation function requires analyzing whether aqueous fluid specifically flows through the trabecular meshwork tissue in the eye. Ex. 24, 9/28 Downs Tr. 99:15-25; 107:5-108:12; 147:22-149:3; Ex. 15, Downs Reb. Rep. ¶¶ 147, 149, 150, 178. In other words, Sight's expert opines that increased outflux and decreased intraocular pressure (IOP), which Sight previously described as "benchmarks" showing "the absence of 'substantial interference,'" are insufficient to predict whether or not a device achieves the Block Limitation function. D.I. 118 at 25; D.I. 118 at 27 (similar); *see also* D.I. 119 Ex. 20 at 141:18-142:8; Ex. 24, 9/28 Downs. Tr. 147:9-149:3. Sight's expert also opines that prior art supports—including physical implants that reduced IOP in live patients—do not satisfy the Block Limitation.

[4] Sight claims its Helix "would embody at least the independent asserted claims of the '482 patent" that recite the Block Limitation, but has not explained how it allegedly knows this. Ex. 58, Plaintiff's Obj. and Resp. to Defendants' Interr. No. 14 at 22.

See, e.g., Ex. 15, Downs Reb. Rep. §§ VII.D.1.c(4), VII.E.1.c(4); *cf., e.g.*, Ex. 41, Bahler 2004 (discussing IOP-lowering effect of two bypass devices: EyePass (GMP bi-directional glaucoma shunt) and iStent ("L-shaped" device)); Ex. 31, Lynch-197 at 1:4-10, 9:1-8, 19:19-24.[5] Thus, Sight's expert confirms the field's unpredictability because, in his opinion, the IOP reduction of increased aqueous outflow "benchmarks" would not give a POSA enough information to determine whether the "support" satisfies the Block Limitation. *See In re Fisher*, 427 F.2d at 839.

The specification's direction, guidance, or working examples. "A specification that requires a POSA to 'engage in an iterative, trial-and-error process to practice the claimed invention' does not provide an enabling disclosure." *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1161 (Fed. Cir. 2019); *see also Amgen*, 598 U.S. at 600, 611, 614. The specification of the Asserted Patents discloses ***no*** examples of any functional device, ***no*** modeling of flow or IOP reduction for any supports, ***no*** flow calculations, and ***no*** analysis of whether or not any disclosed device would achieve the Block Limitation function (or what features, if any, would *necessarily* achieve it). Ex. 24, 9/28 Downs Tr. 66:21-67:15; 77:19-79:21.

Sight's and its expert's shifting-sands understanding of the Block Limitation function further demonstrates the lack of guidance in the specification. For example, Sight's expert conceded that the method Sight argued could determine whether a support "does not significantly block flow"—"conducting pressure gradient studies of the support in cadaver eyes" (D.I. 118 at 26)—is not in the specification. Ex. 24, 9/28 Downs Tr. 78:16-20. Sight's expert then contends computational or analytical modeling—also not in the specification—"would give you an estimate for how aqueous would flow in vivo." *Id.* 65:11-24; 83:14-84:22. Even if true, that modeling can

[5] Paradoxically, Sight's expert relies on clinical studies of Defendants' Hydrus Microstent showing IOP reduction as evidence Defendants infringe this limitation. *See* Ex. 14, Downs Op. Rep. § VIII.A.1.iii.6.

have "lots of different parameters" and a "whole host" of assumptions; these too are not in the specification. *Id.* 77:19-79:21; 83:14-84:22.

As explained above, the specification provides no guidance on any "quality common" to all "supports" for a POSA to predict from the structure alone whether the support would achieve the Block Limitation function. It would instead require trial-and-error modeling or testing of each iteration of the claimed supports to "***estimate***" the *in vivo* IOP reduction or increased outflow. *Id.* 65:11-24; 83:14-84:22; 86:6-19, 88:1-22, 98:10-100:11, 103:5-15. And none of that modeling or testing is disclosed in the specification. The dearth of guidance in the specification, coupled with the unpredictability and need to test for whether a support will achieve the Block Limitation function, demonstrates a lack of enablement.

The amount of experimentation necessary. [redacted] Sight's expert testified that a POSA would have to undertake an extensive "winnowing" approach of repeated trial and error to arrive at supports that ***may*** achieve the Block Limitation function, which involves (1) starting with all possible supports, (2) conducting a computational or analytical model of each support to provide "a workable set," (3) "likely prototyp[ing]" the "candidates" or "workable set" of supports, and finally (4) "try[ing] them in perfusion experiments in cadaver eyes" or testing them in "a large animal model." Ex. 24, 9/28 Downs Tr. 86:6-19, 88:1-22, 98:10-100:11, 103:5-15. Even with this extensive and costly "winnowing" process, Sight's expert conceded it only "***could***," not necessarily would, provide a POSA with the full scope of supports that meet the claims. *Id.* 103:19-105:8. This multi-step "winnowing" approach alone renders the claims invalid because it "amount[s] to little more than [a] research assignment," a "trial-and-error method for finding functional [supports]—calling on

scientists to create a wide range of candidate [supports] and then screen each to see which happen to [not significantly block fluid flow]." *Amgen*, 598 U.S. at 614. "That is not enablement. More nearly, it is a 'hunting license.'" *Id.* (affirming JMOL of invalidity for lack of enablement)*; see also Baxalta*, 2023 WL 6135930, at *4 (affirming summary judgment for lack of enablement for claims requiring "trial and error" screening process that "leaves the public no better equipped to make and use" the full scope of the invention and "constitutes unreasonable experimentation").

Sight's assertion that its winnowing process is "routine," Ex. 24, 9/28 Downs Tr. 67:9-15, 79:3-22; 103:19-104:11, 116:15-117:8, says nothing more than that a POSA can run the process, which is not the enablement standard. Instead, a POSA must be able to make and use the full scope of the invention without ***undue*** experimentation, *Amgen*, 987 F.3d at 1087, and when "'practicing the full scope of the claims would have required excessive experimentation, even if routine,' the patent is invalid for lack of enablement." *Idenix*, 941 F.3d at 1163 (quoting *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013)). Sight's "routine" "winnowing" process requires excessive trial-and-error, modeling countless permutations of supports with different configurations, shapes, materials, shapes, lengths, radii of curvature, and other possible variables, and then testing those models to determine which permutation of variables, if any, may achieve the Block Limitation function. Ex. 24, 9/28 Downs Tr. 35:7-25; 98:10-100:11. It then requires perfusion studies, which would require acquiring cadaver eyes from an eye bank and running tests that take anywhere from hours to days to complete ***for each eye***. *See* Exs. 54-55, SGHT0161700 at 702-703 (showing perfusion studies up to 193 hours); Ex. 41, Bahler 2004 (describing a 5-day perfusion study); Ex. 24, 9/28 Downs Tr. 98:10-100:11, 105:23-106:5, 114:25-115:6. Additionally, ***each*** study costs "quite a bit of money," upwards of "several thousand dollars." Ex. 25, D. Badawi Tr. 122:23-123:14; Ex. 24, 9/28 Downs Tr. 117:13-119:9. Even assuming perfusion

studies are "routine," they require "excessive experimentation," confirming the patents are not enabled. *Idenix*, 941 F.3d at 1163; *see also Amgen*, 598 U.S. at 614 ("'painstaking experimentation' to see what works…is not enablement").

Finally, the inventors' failures and shortcomings with respect to creating a Schlemm's canal implant further evidence a lack of enablement. *Novo Nordisk Pharms., Inc. v. Bio-Technology Gen. Corp.*, 424 F.3d 1347, 1362 (Fed. Cir. 2005) ("[A]n inventor's failed attempts to practice an invention are relevant evidence of non-enablement"); *see also Liebel-Flarsheim*, 481 F.3d at 1379 (missing a prototype factored into lack of enablement). [redacted] have no commercialized product that embodies any of the Asserted Patents. Ex. 25, D. Badawi Dep. Tr. 164:9-17; Ex. 26, P. Badawi Tr. 146:7-11, 166:10-20; Ex. 59, Plaintiff's Obj. and Resp. to Defendants' RFA Nos. 4 and 5; Ex. 58, Plaintiff's Obj. and Resp. to Defendants' Interr. No. 14 at 21-22.

[redacted]. Ex. 55, SGHT0161701-703; Ex. 25, D. Badawi Tr. 184:2-185:5. [redacted] Ex. 53, SGHT0116857-66; *see also* Ex. 51, NIH funding application; Ex. 26, P. Badawi Tr. 161:16-162:9, 165:23-166:20 [redacted] These attempts and failures to create "a commercial product that purports to be an embodiment of the patented invention, [] is strong evidence that the patent specification lacks enablement." *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1318–19 (Fed. Cir. 2007). [redacted]

[redacted]. *Compare* Ex. 1, '482 Patent Figs. 8E-F *with* Ex. 29, ADMEDES00115-116 ([redacted]) confirms the specification is not enabling, but a hypothesis to be tested, or at best "only a starting point, a direction for further research." *Auto. Techs. Int'l v. BMW of N. Am.*, 501 F.3d 1274, 1284 (2007); *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

Applying the *Wands* factors. The claims broadly cover a "support" defined by its Block Limitation function, but the specification lacks any correlation between the support's structure and its function. Sight's expert admits a POSA would need to engage in modeling, prototyping, and experimenting through studies that take from hours to days and cost thousands of dollars, all to arrive as a ***potential subset*** of supports that ***may*** achieve the Block Limitation function. The Block Limitation claims are therefore invalid for lack of enablement as a matter of law and summary judgment should be granted. *Amgen*, 598 U.S. at 614; *see also id.* at 616.

B. Motion 2: The Block Limitation Claims Are Invalid for Lack of Written Description Because the Specification Does Not Demonstrate That the Inventors Actually Invented the Full Scope of Supports That Achieve The Claimed Function.

In addition to the enablement requirement, every patent specification must "contain a written description of the invention." 35 U.S.C. § 112; *see also Ariad*, 598 F.3d at 1344 (holding enablement and written description as distinct requirements). Like the enablement requirement, the written description requirement "is part of the *quid pro quo* of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time." *Id.* at 1354. Patents are awarded "to those who actually perform

the difficult work of 'invention'…and disclose the fruits of that effort to the public." *Id.* at 1353.

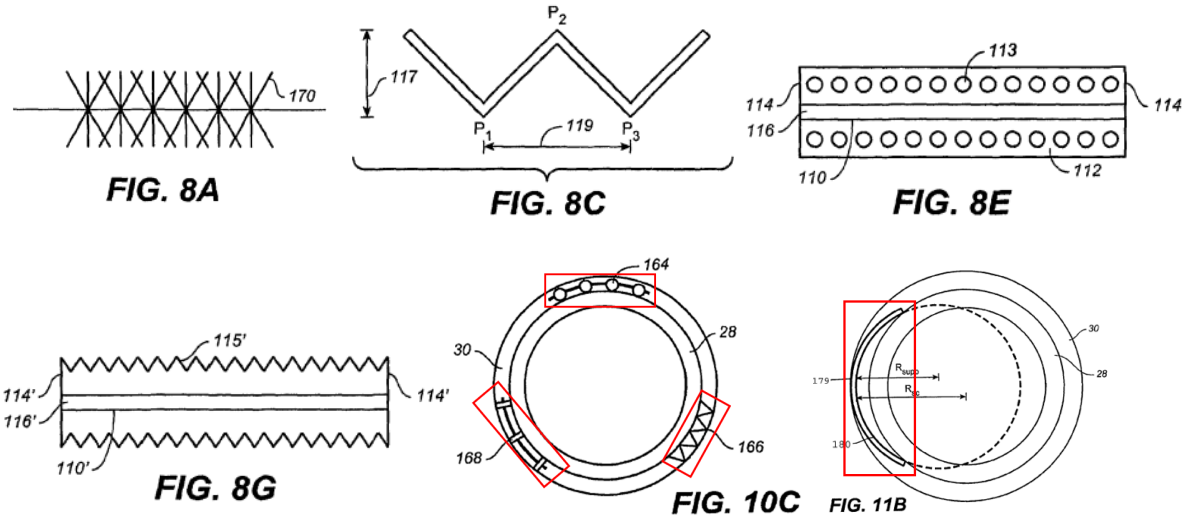
An adequate written description must "describe an invention understandable to [a] skilled artisan and show that the inventor actually invented the invention claimed" as of the patent's priority date. *Id.* at 1351. "[T]he hallmark of written description is disclosure." *Id.* "For genus claims using functional language, like the ['does not significantly block'] function of the ['supports'] here, the written description must demonstrate that the [patentee] has made a generic invention that achieves the claimed result." *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1335 (Fed. Cir. 2021) (quotations and citations omitted). To do this, a specification can disclose "either a [1] representative number of species falling within the scope of the genus or [2] structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus" and distinguish them from those outside the genus. *Id.*

The written description of the Asserted Patents is woefully deficient because it provides no indication that the inventors actually invented the immeasurable swath of "supports" or any "representative species" of "supports" that achieve the Block Limitation. *Id.* The specification is instead a "mere wish or plan" for obtaining a huge genus of possible supports that "do[] not significantly block," providing ***no*** examples of ***any*** support that actually does so, and requiring testing to determine whether or not the function is achieved. That fails the written description requirement and renders the claims invalid as a matter of law. *Centocor*, 636 F.3d at 1348.

Even Sight's expert admits the specification provides no examples (*e.g.*, through models or studies) of supports that achieve the Block Limitation function. Ex. 24, 9/28 Downs Tr. 74:23-76:18, 77:19-79:21. *See Billups-Rothenberg, Inc. v. Assoc. Reg'l & Univ. Pathologists, Inc.*, 642 F.3d 1031, 1037 (Fed. Cir. 2011) (affirming summary judgment of invalidity for lack of written description, and absence of "even a single species that satisfies the claims" factored into that

determination); *see also Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) ("The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention."). Rather than provide "representative" supports that achieve the Block Limitation function, the specification is no more than a "research hypothesis," describing a "'problem to be solved while claiming all solutions to it ... cover[ing] any [device] later actually invented and determined to fall within the claim's functional boundaries,' which fails to satisfy the written description requirement." *Juno*, 10 F.4th at 1339 (quotation omitted).

Nor does the specification provide any "structural features common" to supports to which a POSA could attribute the Block Limitation function. *Juno*, 10 F.4th at 1335. Indeed, the specification and non-exhaustive Figures boast the diversity of possible structural features, rather than any commonality or representativeness. *See supra* n.2.



Ex. 1, '482 Figs. 8A, C, E, G, 10C, 11B; *see also id.* Figs. 5B-C, 6A-7E, 9A, 10A-B, 11A, 11C.

Sight's expert contends the specification's discussion of "minimal support contact with canal walls" is a common structural feature sufficient to distinguish supports that "do not significantly block" from those that do (Ex. 15, Downs Reb. Rep. ¶ 1110-13; '482 at 11:30-38),

but that opinion is unsupportable. In fact, when deposed, Sight's expert conceded that this feature alone—a lower percentage contact (*i.e.*, "minimal support contact") with canal walls—is ***not*** necessarily indicative of whether the Block Limitation is met. Ex. 24, 9/28 Downs Tr. 129:7-24 (testifying that "you could have a support with, say, 20 percent surface area contact that fully blocks the TM" and would not meet the Block Limitation).

Moreover, "minimal support contact" cannot satisfy the written description requirement for at least three additional reasons. ***First***, the specification equivocates, positing that "[i]f a substantial portion of the surface area" of certain areas of the canal are "blocked, effective fluid flow across the canal ***may be*** impaired." Ex. 1, '482 at 11:30-38. ***Second***, there are ***some*** claims that already recite specific "minimal support contact" percentages: less than 30%, 10% and 1%. *See, e.g.*, *id.* cls. 1, 24, and 25. Because these features do not appear in ***all*** claims, they cannot be used to determine whether the claimed "support" in ***every*** claim achieves the Block Limitation. ***Third***, Sight's expert asserts that Figures 5B-12H are "exemplary images of supports with minimal surface area contact," but he did not even analyze whether those supports meet the surface area contact limitation and could only make an "educated guess" that Figure 9A would "not substantially interfere with flow." Ex. 24, 9/28 Downs Tr. 130:14-132:4; 132:15-134:11.

The Asserted Patents disclose no species of supports that are representative of the vast universe of possible candidates for a support that achieves the claimed Block Limitation function, nor structural commonality for such a support. The Block Limitation claims are invalid as a matter of law because the specification provides no examples or "precise definition, such as by structure,…physical properties, or other properties, of species falling within the genus" for a POSA to "'visualize or recognize' the members of the genus" of supports that "do not significantly block" flow and distinguish them from supports that do. *Ariad*, 598 F.3d at 1350; *see also Idenix*, 941

F.3d at 1164-65 (reversing denial of JMOL for failure to meet the written description requirement when there was no "meaningful guidance into what compounds beyond the examples and formulas, if any, would provide the same [functional] result").

The lack of written description is unsurprising—the inventors overreached by claiming all potential solutions to a problem they did not solve. They did not provide the public with "a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time." *Ariad*, 598 F.3d at 1353-54. Because there is no genuine dispute of material fact that the specification fails to demonstrate the inventors actually possessed the claimed invention in the Block Limitation claims, summary judgment should be granted. Fed. R. Civ. P. 56(a).

C. Motion 3: The Block Limitation Claims Are Indefinite Because Sight's Shifting Interpretations of the Claim Language Show That a POSA Would Not Reasonably Be Able to Determine the Scope of the Claims

Summary judgment also is warranted for the independent reason that each Block Limitation Claim is invalid as indefinite. "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014); 35 U.S.C. § 112.

The Asserted Patents provide no detail for a POSA to be reasonably certain when the claimed "supports" "do[] not significantly block" fluid flow when implanted in the eye, a relative and subjective limitation rendering the claims indefinite. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (A "term of degree fails to provide sufficient notice of its scope if it depends on the unpredictable vagaries of any one person's opinion."). This imprecise and undefined scope is further emphasized by Sight deploying a new construction through its rebuttal expert reports. Sight's new membrane-specific interpretation of Block Limitation claims confirms a POSA would not have been reasonably certain of the scope of the claims because a

POSA would not have been able to do that flow analysis as of the priority date (or even now).

First, under the Court's construction, a POSA would not have been able to reasonably determine when a support "significantly blocks" fluid flow when implanted. *Bombardier Rec. Prods. Inc. v. Arctic Cat Inc.*, 785 F. App'x 858, 867-68 (Fed. Cir. 2019). The claims are generally directed to devices for achieving results *in vivo*. While a POSA could have measured intraocular pressure, which varies from patient to patient, a POSA could not measure any "blocking" of fluid *in vivo*. Ex. 24, 9/28 Downs Tr. at 107:5-109:16 (perfusion studies are not done in patients); 155:2-5 (same); Ex. 25, D. Badawi Tr. 174:24-177:5 (discussing perfusion studies: "the real proof in the pudding is not this, right, because this [perfusion study] is an ex vivo system"); Ex. 24, 9/28 Downs Tr. at 157:14-158:13; 155:20-23 (noting "there's some variance" in the "trabecular meshwork permeability" among individuals); Ex. 18, Tanna Rpl. Rep. ¶ 537. Claims are indefinite when "an artisan would not know from one [patient] to the next whether a certain [stent] was within the scope of the claims because a wide variety of factors could affect [flow across the trabecular meshwork]." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1254-55 (Fed. Cir. 2008).

Second, Sight now argues that the very metrics it persuaded the Court to adopt at claim construction—intraocular pressure (IOP) reduction and increased outflow—are ***insufficient*** to determine whether a device "significantly blocks." *Compare* Ex. 24, 9/28 Downs Tr. 107:5-108:12; 147:22-149:3 (opining that the "significantly block" term "requires some flow across—through the trabecular meshwork" and "not around it through a bypass inlet") *with* D.I. 273 at 6; D.I. 119 Ex. 20 at 141:18-142:8 (Sight's expert testifying "whether it's longitudinal or transmural is not that important, other than the fact that it leads to a net increase in fluid efflux."); D.I. 119 Ex. 20 at 141:18-142:8. Sight now ***requires*** that membrane-specific flow must be achieved to meet the Block Limitation, but a POSA would not have been able to measure membrane-specific

"blocking." Ex. 18, Tanna Rpl. Rep. ¶¶ 537-39. Moreover, Sight only adopted this new construction in an obvious attempt to avoid myriad prior art that disclosed Schlemm's canal implants that reduce IOP and increase aqueous outflow. *Compare* Ex. 14, Downs Op. Rep. ¶ 97 (relying on Hydrus experimental data showing increased outflow facility), *with* Ex. 15, Downs Reb. Rep. ¶ 147. In any event, Sight's "cascade of ever-changing meanings…introduces the very imprecision Section 112 prohibits." *Aquatic AV, Inc. v. Magnadyne Corp.*, No. C 14-01931-WHA, 2015 WL 926425, at * 2 (N.D. Cal. Feb. 25, 2015).

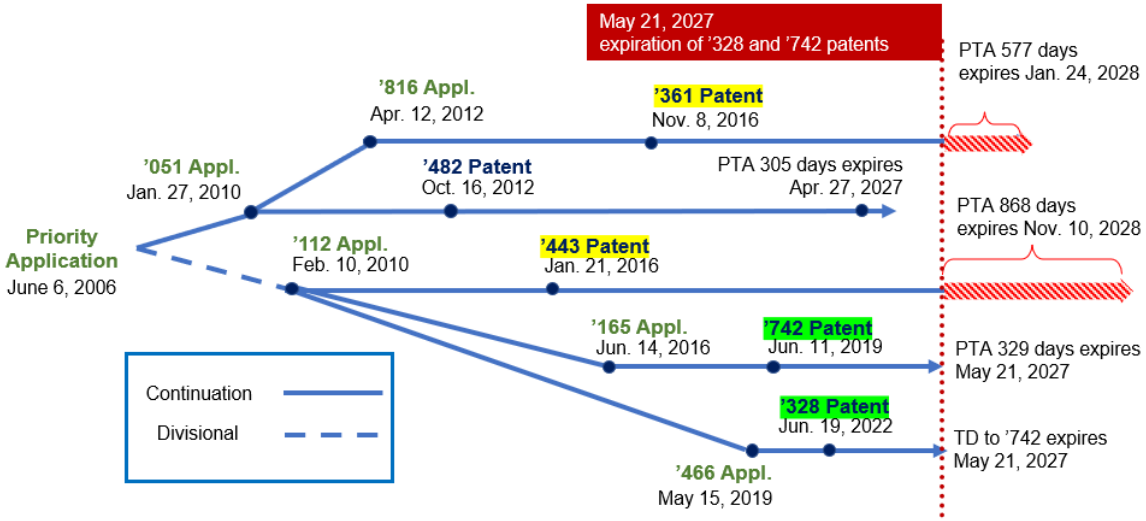
Third, Sight argues that the ***length*** of a bypass device affects whether the membrane-specific fluid flow will occur across the trabecular meshwork, compounding the uncertainty of the scope of the claims. Ex. 15, Downs Reb. Rep. ¶ 170 (arguing that fluid may not flow "near the inlet of the bypass stent," but that "is not likely to hold further away from the bypass stent inlet"). Nothing in the Asserted Patents provides guidance regarding what lengths of a "support" "significantly block" flow and what lengths do not. This "absence of identified boundaries in terms of proximity, distance, or location" further demonstrates that a POSA would not have been reasonably certain about the scope of the claims, which are therefore indefinite. *Abdou v. Alphatec Spine, Inc.*, No. 12-cv-1804 BEN (RBB), 2014 WL 6611422, at *8 (S.D. Cal. Nov. 19, 2014).

D. Motion 4: The '361 and '443 Patents Are Invalid for Obviousness-Type Double Patenting Because They Are Obvious Variants of the Earlier-Expiring '328 and '742 Patents and Impermissibly Extend the Alleged Inventions' Lifetime

ODP "is a judicially-created doctrine designed to prevent claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." *In re Hubbell,* 709 F.3d 1140 (Fed. Cir. 2013). A patent is invalid for ODP if its claims "are not patentably distinct from claims in a commonly owned earlier patent." *Pfizer, Inc.,* 518 F.3d at 1363. A claim is not patentably distinct "if the later claim is obvious over, or anticipated by, the earlier claim." *Eli Lilly*

& Co. v. Barr Labs., Inc., 251 F.3d 955, 968 (Fed. Cir. 2001). "For a patent to qualify as an [ODP] reference, its expiration date must fall before that of the challenged patent." *Allergan USA, Inc., et al. v. MSN Lab. Private Ltd., et.al.*, No. CV 19-1727-RGA, 2023 WL 6295496, at *22 (D. Del. Sept. 27, 2023). On August 28, 2023, the Federal Circuit held that "the expiration date used for an ODP analysis where a patent has received [a patent term adjustment (PTA)] is the expiration date after the PTA has been added." *In re: Cellect, LLC*, 81 F.4th 1216, 1226 (Fed. Cir. 2023). Thus ODP now applies to earlier-filed patents with later expiration dates than other patents in the family because of PTA. Indeed, this District has recently applied *Cellect* to find an earlier-filed but later-expiring patent due to a PTA invalid for ODP. *Allergan*, 2023 WL 6295496, at *22.

There is no dispute that the '361 and '443 patents expire after the '742 and '328 patents: the '328 and '742 patents expire in May 2027, while the '361 and '443 patents expire in January and November of 2028, respectively, as illustrated by Appendix Y below.[6] Exs. 2-5 ('443, '361, '742, '328 patents) at cover; Ex. 10, Jarosz Op. Rep. at ¶¶28, 29, 31, 33; Appendix Y.



[6] The '361, '443, '328, and '742 patents are part of the same family, sharing the same priority date, and therefore would typically expire at the same time. However, as illustrated in Appendix Y, these patents received PTAs that cause them to expire at different times, resulting in an impermissible windfall to the terms of the '361 and '443 patents.

There is also no genuine dispute that the claims of the '361, '443, '328, and '742 patents are not patentably distinct, as a simple comparison of their claims confirms:

'361 Patent	'328 Patent
1. A method for reducing intraocular pressure, comprising: introducing a tubular cannula having a lumen at least partially within Schlemm's canal; delivering a high viscosity fluid into Schlemm's canal; and inserting a support into Schlemm's canal by passing the support through the tubular cannula, wherein the support comprises an arcuate member, wherein at least a portion of the arcuate member has a radius of curvature smaller than a radius of curvature of Schlemm's canal, and wherein the support comprises at least one fenestration.	1. A method for reducing intraocular pressure in a patient using a support and an introducer comprising a cannula, comprising: positioning a distal end of the cannula at or near Schlemm's canal, wherein the support is located in a lumen of the cannula; and pushing the support distally out of the distal end of the cannula to insert the support circumferentially within Schlemm's canal, wherein the support comprises an arcuate member, wherein at least a portion of the arcuate member has a radius of curvature R_{supp} smaller than the radius of curvature of Schlemm's canal such that at least a portion of the arcuate member extends out of Schlemm's canal. 4. The method of claim 1, further comprising dilating Schlemm's canal prior to inserting the support. 5. The method of claim 4, wherein Schlemm's canal is dilated by injecting fluid into the canal. 22. The method of claim 1, wherein the support comprises at least one fenestration. 23. The method of claim 1, wherein the support comprises a plurality of fenestrations.

'443 Patent	'742 Patent
1. A device for reducing intraocular pressure in an eye having a Schlemm's canal and a trabecular meshwork, comprising: a support implantable circumferentially within Schlemm's canal and configured to maintain the patency of at least a portion thereof, wherein the support comprises an arcuate member, wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm's canal so that at least a portion of the arcuate member is configured to extend out of Schlemm's canal and into the trabecular	1. A method for treating an eye condition, comprising: implanting a support within Schlemm's canal, wherein the support comprises an arcuate member, wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm's canal such that at least a portion of the arcuate member extends out of Schlemm's canal. 13.The method of claim 1, wherein when the support is disposed within a cylindrical section of the lumen of Schlemm's canal having an internal wall surface area C, the support contacts less than 30% of C.

'443 Patent	'742 Patent
meshwork and wherein the support does not substantially interfere with transmural flow across Schlemm's canal, and wherein when the support is disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of C.	17. The method of claim 1, wherein the support does not substantially interfere with longitudinal flow along Schlemm's canal. 18. The method of claim 1, wherein the support does not substantially interfere with transmural flow into and out of Schlemm's canal.

See also Appendix X (charts comparing of all asserted claims of the '361 and '443 patents).

Indeed, Sight itself repeatedly confirmed the claims are not patentably distinct to the PTO during prosecution of the '328 and '742 patents. The Examiner rejected the then-pending claims of those patents for ODP because they were "not patentably distinct from" the claims of the '361 and '443 patents. ODP CSoF at ¶¶ 5, 7. Sight filed terminal disclaimers for the '328 and '742 patents to overcome the Examiner's ODP rejections, which "is a strong clue that the claims … are patentably indistinct." *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, 752 F. App'x 1024, 1035 (Fed. Cir. 2018); ODP CSoF at ¶¶ 5, 7.

Sight then doubled down on the similarity of claims when it asked the PTAB to deny institution of Defendants' petitions for *inter partes* review ("IPR") of the '361 and '443 patents. Sight argued that the PTAB should deny institution because Defendants' prior art had been before the PTO during prosecution of the '328 and '742 patents, and those patents' claims were of "similar scope" to the '361 and '443 patents' claims. ODP CSoF at ¶¶8–10. To convince the PTAB that these claims were of "similar scope," Sight adopted the Examiner's holding that "[a]lthough the claims at issue are not identical, ***they are not patentably distinct from each other***." *Id*. Indeed, Sight charted for the PTO the similarity of exemplar claims in the '361, '443, '328, and '742 patents—making virtually identical comparisons as Defendants' chart above. *Id*. Sight is bound by its representations to the PTO; it cannot "argue[] one way in order to maintain [its] [claims'] patentability and in a different way against accused infringers." *Aylus Networks, Inc. v. Apple Inc*.,

856 F.3d 1353 (Fed. Cir. 2017).

No genuine dispute of material fact therefore exists, and the '361 and '443 patents are invalid for ODP. *Cellect*, 81 F.4th at 1226 (when "the claims of a later-expiring patent would have been obvious over the claims of an earlier-expiring patent owned by the same party…absent a terminal disclaimer, the later-expiring claims are invalid."). Accordingly, the Court should grant summary judgment that the '361 and '443 patents are invalid for ODP.

IV. CONCLUSION

Defendants respectfully request that the Court grant summary judgment that the Block Limitation claims are invalid and that the '361 and '443 patents are invalid for obviousness-type double patenting for the reasons presented above.

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Dated: October 12, 2023

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